

Applicant : David R. Hennings, et al.
Appl. No. : 10/699,212
Examiner : David M. Shay
Docket No. : 15487.4002

REMARKS

The Office Action dated May 17, 2006 has been carefully considered. While Applicants do not agree that claim 36 involves new matter, claim 36 has been cancelled to remove the new matter issue from further prosecution of this application.

Claims 1, 2, 6, 7, 25, 35-38, 40, 41 and 44-46 have been rejected as unpatentable over Goldman '084 in combination with the newly-cited Sinofsky reference and the previously-cited Dew reference. Sinofsky discloses laser systems having a wavelength range of approximately 1.4-2.15 micrometers. The Examiner's statement of his rejection suggests that Applicants are claiming to be the inventors of lasers which emit energy in the claimed range of about 1.2 to about 1.8 micrometers. This is not so. Applicants' method claims, e.g., claims 1-14, recite a method of "treating varicose veins" to destroy the functionality of the vein. Sinofsky's method is directed to the diametrically opposite purpose of improving the functionality of blood vessels by removing atherosclerotic plaque by treatment with a laser. These two methods are the antithesis of each other. Thus, Sinofsky is totally irrelevant and, if anything, teaches away from the purpose of both Applicants and of Goldman. As such, Sinofsky cannot rationally be combined with Goldman.

Furthermore, since Sinofsky discloses wavelengths which encompass those, e.g., 1.32 micrometers, of Dew, these references appear to be redundant. The Examiner's assertion that the method of Dew, which has nothing to do with varicose veins, can destroy the proteins, but allow near normal tissue to take its place is, as Applicants have previously indicated, a repair process which, once again, is the diametric opposite of the invention claimed by Applicants. Thus, it appears plain that the rejection is based on a combination of references in an attempted reconstruction of Applicants' invention by combining the uncombinable.

As acknowledged by the Examiner, Goldman, who makes only passing reference to the use of a laser, discloses no wavelengths. In the real world, those attempting to use lasers to accomplish the purpose of Goldman deliberately chose not to use the wavelengths claimed by Applicants. The Examiner also acknowledges this to be a fact. Those skilled in the art with motivation to use a laser to treat varicose veins chose to use laser wavelengths of 0.81 to 1.064 micrometers for which blood is a chromophore and did not consider it desirable to use Applicants' wavelengths for which water is a chromophore. Thus, the other workers used

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wavelengths between 0.81 and 1.064 micrometers rather than 1.2 to 1.8 micrometers for a reason, and that reason teaches away from Applicants' invention.

Furthermore, the Examiner's characterization of the Min et al. reference as "teaching away from the 1064 nanometer wavelength," while accurate, does not give effect to the primary teaching of this Min et al. article, which is that the 810 nanometer wavelength is far preferable to the 1064 nanometer wavelength. In other words, Min et al. direct the reader to wavelengths lower than 1064 nanometers. Applicants, on the other hand, have gone in the diametrically opposite direction to higher wavelengths. Thus, once again, in the real world, workers skilled in the art advocated the use of wavelengths less than 1064 nanometers. In these circumstances, it must be concluded that, contrary to the opinion of the Examiner, it was not considered obvious to treat varicose veins with laser energy in the range of about 1200 to about 1800 nanometers.

In addition, the two Proebstle articles previously called to the Examiner's attention also demonstrate that those skilled in the art considered the use of wavelengths in the 810 nanometer to 980 nanometer wavelength range to be desirable for treating varicose veins because those wavelengths target blood, not water. The foregoing discussion applies to all of the claims rejected as unpatentable over Goldman '084 in combination with Sinofsky and Dew.

Claims 3-5, 42 and 43 have been rejected as unpatentable over the foregoing three references in further combination with Roth. As Applicants have repeatedly acknowledged, Roth discloses a pull back feature but in no ways cures the deficiencies of the combination of Goldman '084 with Sinofsky and Dew. In making this rejection, the Examiner makes the statement that the "problem of tissue adhesion is notorious in the art" and that "official notice" of that problem is "hereby taken, thus producing a method such as claimed." It is believed that this statement by the Examiner comes within the scope of 37 C.F.R. 1.104(d)(2) which provides that "when a rejection ... is based on facts within the personal knowledge of an employee of the Office" the applicant is entitled to request the affidavit of such employee. Applicants hereby request such an affidavit and, as required by 37 C.F.R. 1.104(d)(2), of the data or reference relied upon by the Examiner. In particular, such data or reference should be directed to a pull back rate of between about 0.1 mm/sec to about 10.0 mm/sec and to beginning the retraction of the fiber optic laser prior to initiating delivery of the laser energy.

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Claims 8 and 39 have been rejected over Goldman '084, Sinofsky and Dew in further view of Conn. Applicants do not claim to be the inventors of a diffuser tip for a laser, which is all that Conn discloses. Conn does not cure any of the deficiencies of the combination of Goldman '084 with Sinofsky and Dew.

Claims 9-13 have been rejected as unpatentable over Goldman, Sinofsky and Dew in combination with Makower. Applicants do not claim to be the inventors of controlling the heating of tissue by using infrared sensing, which is all that Makower discloses. Thus, Makower does not cure any of the deficiencies of Goldman in combination with Sinofsky and Dew.

Claims 14-17 and 20-23 have been rejected as unpatentable over Makower in combination with Roth and Dew. Once again, this rejection combines references which are not combineable. As disclosed at page 8 of Makower and as illustrated in Figure 1, the Makower device is provided with locking means 16 which is actuated during treatment. If a pull back device such as that of Roth were used, the result would be pulling the prostate out of the body through the urethra, a distinctly unpleasant event for the patient. Thus, Makower and Roth cannot be combined. Furthermore, even though it is true that Makower discloses the use of an Nd:YAG laser, this laser does not, as stated by the Examiner, "necessarily" produce radiation in the claimed range. This is stated in the Dew reference itself at column 6, lines 11-13 where Dew states:

"Absent any tuning of the laser cavity, Nd:YAG lasers will emit light at a fundamental dominant wavelength of 1.06 micrometers."

In addition, Dew states that such lasers cannot emit light at a wavelength of 1.32 micrometers unless the dominant emission is suppressed. There is absolutely no disclosure in Makower about suppressing the normal radiation of such a laser. Thus, it is incorrect for the Examiner to state that it is necessary that such lasers will emit light in the 1.2-1.8 micrometer range.

Claim 19 has been rejected as unpatentable over Makower in view of Dew, Roth and Conn. Conn simply adds a defusing tip which is something the Applicants do not claim to have invented. It does nothing to remedy the deficiencies described above in the combination of Makower, Roth and Dew.

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CONCLUSION

The claims of this application have, we submit, been demonstrated to be patentable. The objective of evidence of the activity of those skilled in the art establishes that they believed that targeting blood, not water, was the approach to be used in treating varicose veins with laser energy. The only reference cited by the Examiner directed to the treatment of varicose veins is Goldman and Goldman contains no disclosure whatsoever with regard to laser wavelength. Navarro Patent No. 6,398,777 demonstrates that those attempting to use lasers to treat varicose veins considered wavelengths from 532 to 1064 nanometers to be appropriate. While this reference goes far beyond Goldman '084, which makes only passing reference to the use of lasers to treat varicose veins, and contains a greatly expanded discussion of the use of lasers to treat varicose veins, it has not been cited by the Examiner. It is, however, along with the articles cited to the Examiner, a reflection of the real world of those skilled in the art. However, instead of giving effect to that real world, the Examiner has attempted to reconstruct the claimed invention by combining Goldman with references that have nothing to do with treating varicose veins. It is respectfully submitted that these references cannot be properly combined and that all of the claims are patentable. A favorable action is respectfully solicited.

The Commissioner is authorized to charge the three-month extension fee of **\$510.00** and any fee which may be required in connection with this Amendment to deposit account No. 15-0665.

Respectfully submitted,

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